



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,416	07/08/2002	Joseph Simcha Wolnerman	082864-000000US	8949

7590 09/05/2003

Joe Liebeschuetz
Townsend & Townsend & Crew
8th Floor
Two Embarcadero Center
San Francisco, CA 94111-3834

EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 09/05/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,416

Applicant(s)

WOLNERMAN, JOSEPH SIMCHA

Examiner

Patricia A Patten

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-29 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 16-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the election of species requirement in Paper No. 13 is acknowledged. The traversal is on the ground(s) (1) that the term 'three unsaturations' means either with two double bonds or with a ring on the structure. Applicant contends that because this definition was given in the Specification, that the claims indeed have unity of Invention; and (2) that Carnallite contains KCl, $MgCl_2$ and NaCl.

(1) Applicant's arguments are persuasive. It is clear that the Specification has defined the term 'three degrees of unsaturation' to mean a compound having three double bonds, or alternatively two double bonds and a ring (as is the case with limonene).

(2) This is not found persuasive because as evidenced by the reference submitted by Applicant, $KCl \cdot MgCl_2 \cdot 6H_2O + NaCl$ is Carnallite and not Carnallite.

Therefore, it is apparent that 'Carnallite' does not contain NaCl, and therefore, the presence of dependant claims which state Carnallite do not share the same special technical feature as displayed in claim 1. Further, Carnallite is a complexed structure, which does not correspond to the single salts as listed in Claim 1.

Art Unit: 1654

Because the claims lack a special technical feature, the Restriction requirements of 1/27/03 (Paper No.9) and 6/11/03 (paper No.12) remain proper (with the exception of the reasoning set forth for the election of species between the monoterpenes with three unsaturations). This requirement is therefore made FINAL.

Claims 16-29 were withdrawn from further consideration on the merits as being drawn to a non-elected invention in Paper No. 12. Claims will be searched on the merits as they pertain to $MgCl_2$, and dependant claims not specifically drawn to $MgCl_2$ will be withdrawn from consideration as being drawn to a non-elected invention. Namely, claims 11 and 12 are withdrawn from examination on the merits as they are drawn to a non-elected species.

It is noted that during a search for the elected species, 102(b) art was found on the species of Calcium chloride. Therefore, both of these species were searched on the merits.

Claims 1-10 and 13-15 were examined on the merits.

Priority

This application lacks the necessary reference to the prior PCT application as well as the foreign priority. A statement reading "This is a 371 of PCT/IL01/00276 filed

Art Unit: 1654

03/22/2001 which claims benefit of foreign priority to Application number 135.220 filed in Israel on 3/22/2000." should be entered following the title of the invention or as the first sentence of the specification.

Specification

The use of the trademark Jambus (p.12) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Page 16, two lines under the title 'Effect on Leishmania major promastigotes', there is a phrase which recites 'The drugs were added in 2?l'. It is unclear what '2 ? l' means (this appears to be a typographical error).

Correction is necessary.

Claim Objections

Claims 1 and 3 objected to because of the following informalities.

Claim 1, line 2, recites 'at least 70% by weight monoterpenes'. This phrase is grammatically awkward. It is suggested that an 'of' be placed between 'weight' and 'monoterpenes' in order to correct the structure of this phrase.

Claim 1, lines 3 and 4 recite 'in combination with a suitable carrier said composition'. In this case, a comma should appear after the object of the preposition; 'carrier'.

Claim 3 lines 1 and 2 recite 'wherein said monoterpenes with three unsaturations is..'. The 'is' should be replaced with 'are' in order to conform to the previous plural recitation of 'monoterpenes'.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treatment of oral disease, does not reasonably provide enablement for a composition for preventing oral disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or

Art Unit: 1654

unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective prevention for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

It is noted that the term 'prevention' is deemed to be a 'cure' since prevention of a disease is interpreted to mean that the disease will cease to exist after administration of the drug.

In the Instant case, Applicants have claimed compositions for 'topical, oral administration for prevention and treatment of oral disease'. While it is accepted that the composition will beneficially treat oral disease by hindering the oral growth of some bacteria which cause tooth decay and/or plaque, the Instant specification has not provided enough information to enable the use of preventing oral disease.

The state of the prior art shows that although treatments for oral disease are abundant, prevention of oral disease as a whole is rare. Many bacteria are known for infiltrating the mouth which eventually lead to tooth decay and/or gum disease. For example, Moran (US 6,496,998 B2) states that "Tooth decay begins when acid products of bacteria dissolve the apatite crystal bundles of enamel. Sucrose in the diet, under the influence of *Streptococcus mutans*, is converted into a sticky polysaccharide....The *S. mutans* group of bacteria ...coexist with blood cells, ions and immunoglobulins in the saliva. *S. mutans* creates an acid media in the plaque in which colonies and aggregates of mixed colonies of different bacteria flourish" (col.5, lines 14-34). One such 'different bacteria', as disclosed by Moran, is *Lactobacillus* (col.5, lines 35-46).

There is no indication in the Instant Specification that the composition is effective in preventing the growth of *S. mutans*, *Lactobacillus* which are common infections in the dental/oral cavity and produce decay. Although Applicants have provided examples wherein the composition including carnallite inhibited growth of *F. nucleatum* and *P.gingivalis*, these bacteria are not representative of all bacteria which cause oral/tooth decay. On the contrary, *S.mutans* and *Lactobacillus* are different genus of bacteria which grow and divide differently than *F. nucleatum* or *P.gingivalis*. Thus, although the composition prevented *P.gingivalis* and *F.nucleatum*, the skilled artisan would not have any expectation that the composition would inhibit the growth of *S.mutans* or *Lactobacillus*.

Art Unit: 1654

Thus, the Instant specification has not provided the skilled artisan with the information needed to use the composition within the scope of the claimed invention. Because of this lack of guidance, the skilled artisan would need to perform undue experimentation in order to ascertain if the composition is effective for the scope of the claimed invention. This experimentation would be undue, especially considering that the skilled artisan would not have a reasonable expectation of success.

Deletion of the term 'preventing' from the claims will overcome this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'comprising an active agent containing at least 70% by weight monoterpenes with three unsaturations as active agent therein...'. This statement is indefinite for several reasons. First, does Applicant mean that the active agent contains 70% of another active agent? 'As active agent therein' is confusing because the term 'therein' lacks specific antecedent basis; is this pertaining to the active agent, or the composition? Does Applicant mean to claim that 70% of the composition contains

monoterpenes with three unsaturations, or that the composition comprises an active agent which contains 70% of monoterpenes (which means that 30% of the active agent is unknown, and that the composition itself may contain many other constituents)? Because of this ambiguity, the metes and bounds of the claim cannot be clearly determined. Applicant is asked to amend the claim to more clearly convey the intended invention. For purposes of applying prior art, the Examiner has interpreted this claim to mean a composition comprising an active agent, wherein the active agent contains 70% of monoterpenes with three unsaturations. Please note that the 'active agent' is not defined in the Specification, nor in the claim, and therefore this term was given its broadest interpretation within reason. It is pointed out that any phytochemical or group of phytochemicals could be considered an 'active agent' as will be discussed in the rejections *infra*.

Claim 2 recites '...synthetic mixture consisting of limonene, myrcene, a-pinene, b-pinene, sabinene and mixtures thereof..'. This statement is confusing in that it appears that all of the constituents are present, but the recitation of 'and mixtures thereof' leads the Examiner to believe that Applicants may actually wish for this statement to recite a Markush group. However, the claim states 'synthetic mixture' which indicates that the active ingredient is at least two constituents. Therefore, a Markush statement would read 'synthetic mixture selected from the group consisting of limonene, myrcene.....and mixtures thereof'. However, because the claim states 'mixture', this would be an improper Markush group since at least two species would have to be chosen.

Art Unit: 1654

Alternatively, Applicants may wish to delete the phrase 'and mixtures thereof' since the claim already specified that these ingredients were all present in the active ingredient. Further, the statement 'of which at least 60% by weight is limonene' is indefinite. It is unclear what 'of which' pertains to, and therefore this phrase appears to lack antecedent basis. Also, is this 60% by weight of the active ingredient, or 60% by weight of the composition? If Applicant intends for this to mean 60% by weight of the active ingredient, a suggested claim is: 'wherein said active agent is a natural or synthetic mixture consisting of limonene, myrcene, a-pinene, b-pinene and sabinene, wherein at least 60% of said active agent is limonene. For examination purposes, the claim was interpreted in this way; i.e., that all of the constituents are present, and that 60% of the active agent is limonene.

Claim 4, line 2 recites '...and treatment of oral disease comprising an extract of a citrus fruit...'. Does 'comprising an extract' mean that the composition *additionally* comprises an extract? The claim is unclear and confusing. It appears that Applicants may intend for this to mean 'wherein said composition *is* an extract of a citrus fruit...' or 'wherein said active ingredient *is* an extract of a citrus fruit' since there is no disclosure in the Specification of a composition comprising an active ingredient and an extract; the Specification teaches that the active ingredient is an extract of citrus, namely, the aromatic oil of the citrus fruit. Clarification is necessary.

Claims 14 and 15 recite 'in an amount of up to 10% wt/wt' and 'in an amount of up to 2% wt/wt'. 10% by weight to what amount? Does this mean 10% by weight of the carrier or the composition? The metes and bounds of this value cannot be determined, and therefore the claim is indefinite. Although claim 14 states 'in the carrier in an amount of up to 10% wt/wt, the claim is not absolutely clear that this percentage pertains to the weight of the carrier. Applicant is asked to clarify (in the claims) what these values pertain to ; '10% by weight of the carrier' for example, in order to overcome this rejection. For purposes of applying prior art, these claims were examined as if they were drawn to 10% by weight of the carrier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Huzinieć et al. (US 4,681,766) in light of Kekelidze et al. (1974)*.

Claims 1, 3 and 13 are drawn to a composition comprising an active agent containing at least 70% by weight monoterpenes with three unsaturations in combination with calcium chloride.

Huzinec et al. (US 4,681,766) disclosed a chewing gum which contained calcium chloride, gum base (carrier) and lemon oil (Claims 17 and 19).

Kekelidze et al. (1974)* disclosed that the essential oil of lemon (peel) contains a large number of monoterpenes as can be seen in Table 1. Specifically, Kekelidze et al. showed three varieties of lemons which all contained greater than 70% monoterpenes with three unsaturations (limonene, myrcene, α -pinene, β -pinene and sabinene) in the essential oil of the rind (in each instance, the percentage of the individual monoterpene adds up to more than 70% of the total content of the oil). Thus, it is deemed that lemon oil inherently contains a 70% content of monoterpenes with three unsaturations.

It is noted that the 'active agent' in the claim is a very broad term which could potentially mean any agent or group of agents or the oil. With regard to this particular rejection, the Examiner has interpreted the term 'active agent' to mean the essential oil.

* It is noted that this reference was cited merely to relay an inherent property of lemon oil and is not used in the rejection *per se*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1654

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huzinec et al. (US 4,681,766) in view of Delli Santi et al. (US 5,945,088) and Kekelidze et al. (1974).

The teachings of Huzinec et al. (US 4,681,766) were discussed *supra*.

Huzinec et al. did not specifically teach wherein the limonene was present in the 'active agent' at 'at least 60%' (it is noted that although there is ample evidence to conclude that the essential oil of a lemon contains at least 70% monoterpenes with three degrees of unsaturation [as defined by Applicants] thereby making this an inherent property of lemon oil, there is no evidence which substantiates that each sample of lemon oil will always contain 60% limonene. Although Kekelidze et al. disclosed that Novo lemons contain 89% of limonene, Huzinec et al. did not specifically disclose wherein the lemon oil was derived from Novo lemons or the amount of limonene in the lemon oil. Because it appears that the amount of limonene varies from lemon to lemon, this aspect of the claimed invention is found obvious – *infra*, but not anticipated), wherein the extract was an ether oil, wherein the monoterpenes were present in the carrier in an amount of up to 10% by weight of the carrier, or up to 2% by weight of the carrier.

Delli Santi et al. (US 5,945,088) disclosed that "The use of limonene and its derivatives has been used to improve flavor impact and flavor stability in chewing gum compositions" and further that "...limonene and its derivatives has been show to have anti-bacterial effects..." (col.1, lines 38-43). Specifically, Delli Santi et al. explained that limonene masks the flavor of phenols, possibly by acting as an antagonist to phenolic compounds (col.3, lines 24-26).

Kekelidze et al. (1974) taught that Novogruzinskiy (Novo) lemon oil contained 89% of limonene (Table 1).

It is noted that because monoterpenes are volatile oils which impart a flavor, lemon oil is considered an 'aromatic oil' (claim 6).

One of ordinary skill in the art would have been motivated to have substituted the lemon oil flavoring disclosed by Huzinec et al. for the Novo lemon oil disclosed in Kekelidze et al., because the Novo lemon oil contained 89% of limonene and therefore would have offered improved flavor as well as improved antibacterial activity.

It is noted that although claim 7 recites 'wherein said extract is ether oil', that the percentages of monoterpenes in the oil, as well as the percentage of limonene (60%) remain the same. One of ordinary skill in the art would have been motivated to have

Art Unit: 1654

used an ether oil which contained 60% or more of limonene in the composition disclosed by Huzinec et al. in order to improve the flavor and antibacterial properties of the chewing gum.

Optimization of flavoring components in food and pharmaceutical preparations was conventional in the art at the time the invention was made. Therefore, although none of the references taught wherein the monoterpenes were present in the carrier up to 2% or up to 10%, one of ordinary skill in the art would have been motivated to have adjusted the amount of monoterpenes in order to impart varying intensity of flavors to the chewing gum composition (i.e., regular -vs- extra flavor). Variation in flavoring would have suited individual tastes, thereby increasing marketability of the composition.

Claims 1, 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colodney et al. (US 4,241,049) in light of Kekelidze et al. (1974)*.

Colodney et al. (US 4,241,049) disclosed an antibacterial dentifrice which included a magnesium chloride, a cream or gel (carriers) and a flavoring oil (claims 1 and 5). Colodney et al. taught that lemon oil was a suitable flavoring for the dentifrice (col.3 line 65- col.4, line 7).

Art Unit: 1654

As more keenly stated *supra*, Kekelidze et al. (1974)* contains evidence to deem that lemon oil intrinsically contains at least 70% content of monoterpenes with three unsaturations.

Colodney et al. did not specifically disclose an embodiment which included lemon oil with magnesium chloride in a dentifrice.

One of ordinary skill in the art would have been motivated to have combined lemon oil into the composition because lemon oil would have provided suitable flavoring to the dentifrice composition as clearly stated by Colodney et al. Because this was clearly taught by Colodney et al., the ordinary artisan would have had a reasonable expectation that the lemon oil in the composition would have provided suitable, beneficial flavoring. Again, it is noted that it is deemed that lemon oil intrinsically contains at least 70% monoterpenes with three unsaturations.

Claims 1-9 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colodney et al. (US 4,241,049) in view of Delli Santi et al. (US 5,945,088) and Kekelidze et al. (1974).

The teachings of Colodney et al. (US 4,241,049) were discussed *supra*.

Colodney et al. did not specifically teach wherein limonene was present in the lemon oil at 'at least 60% wherein the extract was an ether oil, wherein the monoterpenes were present in the carrier in an amount of up to 10% by weight of the carrier, or up to 2% by weight of the carrier.

Delli Santi et al. (US 5,945,088) disclosed that "The use of limonene and its derivatives has been used to improve flavor impact and flavor stability in chewing gum compositions" and further that "...limonene and its derivatives has been show to have anti-bacterial effects..." (col.1, lines 38-43). Specifically, Delli Santi et al. explained that limonene masks the flavor of phenols, possibly by acting as an antagonist to phenolic compounds (col.3, lines 24-26).

Kekelidze et al. (1974) taught that Novogruzinskiy (Novo) lemon oil contained 89% of limonene (Table 1).

It is noted that because monoterpenes are volatile oils which impart a flavor, lemon oil is considered an 'aromatic oil' (claim 6).

One of ordinary skill in the art would have been motivated to have substituted the lemon oil flavoring disclosed by Colodney et al. for the Novo lemon oil disclosed in Kekelidze et al., because the Novo lemon oil contained 89% of limonene and therefore would have offered improved flavor as well as improved antibacterial activity.

It is noted that although claim 7 recites 'wherein said extract is ether oil', that the percentages of monoterpenes in the oil, as well as the percentage of limonene (60%) remain the same. One of ordinary skill in the art would have been motivated to have used an ether oil which contained 60% or more of limonene in the composition disclosed by Colodney et al. in order to improve the flavor and antibacterial properties of the chewing gum.

Optimization of flavoring components in food and pharmaceutical preparations was conventional in the art at the time the invention was made. Therefore, although none of the references taught wherein the monoterpenes were present in the carrier up to 2% or up to 10%, one of ordinary skill in the art would have been motivated to have adjusted the amount of monoterpenes in order to impart varying intensity of flavors to the chewing gum composition (i.e., regular -vs- extra flavor). Variation in flavoring would have suited individual tastes, thereby increasing marketability of the composition.

* It is noted that this reference was cited merely to relay an intrinsic property of lemon oil and is not used in the rejection *per se*.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

Art Unit: 1654

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

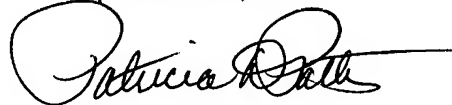
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

September 2, 2003

A handwritten signature in black ink, appearing to read 'Patricia Patten', with a long horizontal flourish extending to the right.

Patricia Patten